



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

007 559,293 11/12/99 GRUPPI

01 21144-106

HM12/0115

CAROL M. GRUPPI
MCLOUTCHEN DOYLE BROWN & ERIKSEN LLP
THREE EMBARCADERO CENTER
SAN FRANCISCO, CA 94111-4566

EXAMINER

CHAI, J

ART UNIT

PAPER NUMBER

1635

12

DATE MAILED:

01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No.

09/439 293

Applicant(s)

CABOT ET AL

Office Action Summary

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1, 3-8, 10-15 & 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3-8, 10-15 & 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 & 10
- 18) ☒ Interview Summary (PTO-413) Paper No(s) 11
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other

Art Unit: 1635

DETAILED ACTION

This Office action is in response to the communication filed October 30, 2000, Paper No. 7, and to the interview with Carol Gruppi, Applicants' representative, on or about January 11, 2001.

Claims 1, 3-8, 10-15 and 17-19 are pending in the instant application.

Withdrawn Objections and Rejections

Rejection of claims 1, 2, 8, 9, 15 and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of Applicants' amendments filed October 30, 2000, Paper No. 7.

Rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Ichikawa et al in view of Lavie et al and further in view of Milner and James is withdrawn in light of Applicants' arguments and amendments, filed October 30, 2000, Paper No. 7.

Retained Rejections

Claims 1, 3-8, 10-15 and 17-29 are rejected under 35 U.S.C. 112, first paragraph, for the same reasons as set forth in the Office action mailed April 26, 2000, Paper No. 5.

Applicants' arguments have been fully considered but they are not persuasive. Applicants argue that the full scope of the claims are enabled by the disclosed specification, whereby the

Art Unit: 1635

expression of glucosylceramide synthase is inhibited in adriamycin resistant cells in vitro following administration of an antisense molecule which targets full length mRNA encoding glucosylceramide synthase, and further whereby antisense treated cells become sensitive to chemotherapeutic agents such as adriamycin. No evidence has been provided in the specification for the successful targeting and inhibition of the target glucosylceramide synthase gene in an organism by antisense which specifically target said gene, and further whereby adriamycin sensitivity is achieved in the appropriate target cell or cells in vivo. No evidence has been provided in the specification for the successful targeting and inhibition of glucosylceramide synthase expression in a target cell in vitro or in vivo by antisense other than using antisense targeting mRNA encoding full length glucosylceramide synthase. Therefore, the full scope of the claims are not enabled by the disclosed specification, which scope comprises compositions and methods for the inhibition of glucosylceramide synthase in any and/or all cells in vitro and in vivo comprising the administration of antisense and further whereby target cells change from adriamycin resistant to adriamycin sensitive cells upon antisense treatment.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-

Art Unit: 1635

3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

January 16, 2001


ANDREW WANG
PATENT EXAMINER
TC 1600